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## Section-by-Section on Discussion Draft of the "Toxic Chemicals Safety Act of 2010" Committee on Energy and Commerce

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### **Section 1. Short Title.**

This Act may be cited as the "Toxic Chemicals Safety Act of 2010."

### **Section 2. Findings, Policy, and Goal.**

This section would amend Section 2 of the Toxic Substances Control Act of 1976 by updating the stated findings, policy, and goal to reflect scientific advances and changes in international chemical regulation.

### **Section 3. Definitions.**

This section would amend Section 3 of the Toxic Substances Control Act of 1976. Definitions for the following terms would be amended: chemical substance, distribute in commerce, environment, health, and safety study, mixture, and new chemical substance. The definition for the following term would be struck: standards for the development of test data. Definitions for the following terms would be added: adverse effect, aggregate exposure, bioaccumulative, chemical identity, cumulative exposure, Federal agency, persistent, substance characteristic, toxic, toxicological property, and vulnerable population.

### **Section 4. Minimum Data Set and Testing of Chemical Substances and Mixtures.**

This section would amend Section 4 of the Toxic Substances Control Act of 1976 to require submission of a minimum data set for all chemical substances and mixtures, which would include information on substance characteristics, hazard, exposure, and use that the Administrator has determined will be useful in carrying out the Act. The Administrator will set out data requirements in a minimum data set rule within one year after enactment. Data sets for all existing chemicals would be required within five years of enactment, and data sets for new chemicals would be required along with the pre-manufacture notice.

This section would also amend existing testing provisions by granting the Administrator the authority to use orders to compel testing. Other Federal agencies would be permitted to request that data developed under this section be shared by the Administrator.

### **Section 5. Manufacture and Processing Notices.**

This section would amend Section 5 of the Toxic Substances Control Act of 1976 by requiring safety standard determinations in the pre-manufacture stage for new chemicals or new uses of existing chemicals that, because of substance characteristics or anticipated production or use, may pose risks to health or the environment. Manufacturers would be required to submit the minimum data set with all pre-manufacture notices, at which point the Administrator would determine whether the substance requires a pre-manufacture safety standard determination or is not reasonably anticipated to present a substantial risk of injury to health or the environment. If the new chemical substance or mixture or new use is reasonably anticipated to present a risk of injury to health or the environment, the Administrator shall complete a safety standard determination within 6 months.

This section would extend the pre-manufacture notice requirement to all new uses, unless the use falls within an exemption, such as the exemption for test marketing.

This section would also require a notice of manufacture or processing, which would be filed no later than 30 days after the date on which the activity commences.

#### **Section 6. Prioritization, Safety Standard Determination, and Risk Management.**

This section would amend Section 6 of the Toxic Substances Control Act of 1976 by establishing a prioritization system and requiring a safety standard determination for chemicals that are prioritized.

This section would require the Administrator to establish a priority list of no fewer than 300 chemical substances and mixtures for which safety standard determinations will first be made. This list would be published in the Federal Register within 18 months after enactment, and updated when a safety standard determination is made or a new chemical substance or mixture is added to the list.

Then, this section would require manufacturers and processors of listed chemicals to submit data enabling the Administrator to make a safety standard determination for all listed chemicals. The Administrator would apply a standard that ensures a reasonable certainty of no harm and protects the public welfare from adverse effects. The manufacturers and processors would bear the burden of meeting the standard.

The determination would be required to be completed not later than 6 months after the submission of all necessary information, and be made publicly available, along with a list of uses and any conditions on those uses necessary to ensure that the safety standard is met. If the determination is made that the chemical substance or mixture has not been shown to meet the safety standard, the chemical would be removed from commerce, subject to exemptions. A determination would remain in effect for 15 years, unless a new use of such chemical substance or mixture is proposed or new information on such chemical substance or mixture warrants a redetermination.

This section would allow manufacturers and processors to request exemptions from risk management for specific uses. The Administrator would be permitted to grant such requests to protect national security, prevent significant disruption of the economy, allow critical or essential uses for which no substitutes are available, or allow uses which provide a net benefit to health or the environment in comparison to alternatives. These exemptions would expire after a period not to exceed 5 years, but could be renewed for one or more additional 5 year periods. Notice of any exemption granted under this subsection would be provided to known purchasers by the manufacturers and processors of the subject chemical substance or mixture, and to the public by the Administrator.

#### **Section 7. Imminent Hazards.**

This section would amend Section 7 of the Toxic Substances Control Act of 1976 to allow the Administrator to issue orders as may be necessary to protect health or the environment from a chemical substance or mixture that may present an imminent and substantial endangerment to health or the environment.

#### **Section 8. Reporting and Retention of Information.**

This section would amend Section 8 of the Toxic Substances Control Act of 1976 to require each manufacturer or processor of a chemical substance or mixture distributed in commerce to provide a declaration of current manufacturing or processing within one year after enactment. This declaration would include the chemical identity of the chemical substance or mixture, data about where manufacture, processing, and distribution occurs, existing health and safety studies, production volume, use, and exposure data, and all other existing information regarding the physical, chemical, and toxicological

properties of the chemical substance or mixture. This declaration would be updated every 3 years, or immediately when there is significant new information.

This section would also require a declaration whenever a manufacturer or processor ceases the manufacture or production of a chemical substance or mixture.

Together, these declarations would be used to create an electronic database to share information about toxicity, use, and exposure to chemical substances and mixtures distributed in commerce. The Administrator would be required to make significant decisions and information available to the public using this database, in keeping with information protection requirements.

#### **Section 9. Relationship to Other Federal Laws.**

This section would amend Section 9 of the Toxic Substances Control Act of 1976 to require the Administrator to submit a report to other Federal agencies when the chemical substance or mixture does not meet the safety standard and when action may be taken to address the use of or exposure to such chemical substance or mixture under laws administered by other Federal agencies. Such reports would be published in the Federal Register and would include requests to the other relevant agencies to determine whether action may be taken under laws they administer, and if so, to initiate such action.

This section would also amend the section to ensure that, if another agency does not take requested action, the Administrator will be able to take any action authorized under the Toxic Substances Control Act to ensure compliance with the safety standard.

#### **Section 10. Inspections and Subpoenas.**

This section would amend Section 11 of the Toxic Substances Control Act of 1976 to allow for inspections and subpoenas under this title.

#### **Section 11. Exports.**

This section would amend Section 12 of the Toxic Substances Control Act of 1976 to provide a timeline for export notice to be submitted by manufacturers and processors to the Administrator and by the Administrator to importing countries for chemicals subject to testing or restriction under the Act. This section also provides a shifted timeline for chemicals listed under the PIC Convention, so that notice will be provided for those chemicals before exportation.

#### **Section 12. Entry into Customs Territory of the United States.**

This section would amend Section 13 of the Toxic Substances Control Act of 1976 by changing a reference to the Secretary of the Treasury to the Secretary of Homeland Security.

#### **Section 13. Disclosure of Information.**

This section would amend Section 14 of the Toxic Substances Control Act of 1976 to require manufacturer substantiation and agency approval of confidentiality claims, to clarify what types of scientific information are not eligible for protected status, and to promote the sharing of confidential information between regulators.

Within one year of enactment, the Administrator would be required to publish standards that specify the acceptable bases for claiming confidentiality – to provide notice and clarity for manufacturers and processors, agency employees, and the public. The Administrator would be required to review all confidentiality requests within 60 days after receipt and decide whether to approve or deny each request. If a request is denied, the Administrator would be required to make the information available to the

public. If a request is approved, the Administrator would specify a time period of not greater than 5 years for which the submitted information would be kept confidential.

This section would also require the Administrator to provide standards for and facilitate the sharing of chemical identity and safety information with workers and their representatives.

#### **Section 14. Prohibited Acts.**

This section would amend Section 15 of the Toxic Substances Control Act of 1976. This section would remove references to specific sections to make clear that it is unlawful to make a false submission under this Act or to fail or refuse to comply with any rule order, prohibition, restriction, or other requirement imposed by this Act or by the Administrator under this Act.

#### **Section 15. Penalties.**

This section would amend Section 16 of the Toxic Substances Control Act of 1976. This section would allow for penalties for any violation under this Act, and increase civil penalties for such violations. The amended section would also include significant criminal penalties for knowing endangerment, similar to provisions in the Resource Conservation and Recovery Act.

#### **Section 16. Specific Enforcement and Seizure.**

This section would amend Section 17 of the Toxic Substances Control Act of 1976 to clarify, but not expand, the EPA Administrator's enforcement authority under the Act. The section would clearly state that the Administrator is authorized to compel compliance with any provision of this Act or any rule or order issued or promulgated under the Act through administrative and civil proceedings.

#### **Section 17. Preemption.**

This section would amend Section 18 of the Toxic Substances Control Act of 1976 to protect the right of states or political subdivisions to impose requirements that are different from or in addition to the requirements of this Act, so long as compliance with both this Act and the state or political subdivision requirement is not impossible.

#### **Section 18. Judicial Review.**

This section would amend Section 19 of the Toxic Substances Control Act of 1976 to ensure that agency action taken under this Act is subject to the same standard as other agency action under the Administrative Procedure Act. Specifically, the section would remove the definition of rulemaking record, which has a general meaning, and remove the exception from general Administrative Procedure Act requirements regarding standard of review.

#### **Section 19. Citizens' Civil Actions.**

This section would amend Section 20 of the Toxic Substances Control Act of 1976 to bring it in line with other citizen suit provisions by clarifying the available relief and allowing suits to address past violations of the Act.

#### **Section 20. Citizens' Petitions.**

This section would amend Section 21 of the Toxic Substances Control Act of 1976 to remove restrictions on the availability of petitions for rules, orders, or other actions authorized under this Act.

#### **Section 21. Employment Effects.**

This section would amend Section 24 of the Toxic Substances Control Act of 1976 to clarify when evaluation is required and the relationship between this section and other provisions of the Act.

**Section 22. Administration of the Act.**

This section would amend Section 26 of the Toxic Substances Control Act of 1976 to allow for increased fees from any person required to submit data under this Act.

**Section 23. State Programs.**

This section would amend Section 28 of the Toxic Substances Control Act of 1976 to establish a process to coordinate with states to share data and priorities.

**Section 24. Authorization for Appropriations.**

This section amends Section 29 of the Toxic Substances Control Act of 1976 to authorize appropriations for each of fiscal years 2011 through 2018.

**Section 25. Additional Requirements.**

This section would amend the Toxic Substances Control Act of 1976 by adding the following new sections:

**Section 32. Risk Assessment for Chemical Substances and Mixtures that are Persistent, Bioaccumulative, and Toxic.**

New section 32 would require the Administrator to promulgate a rule within one year of enactment to establish methodology for tailoring safety standard determinations for chemical substances and mixtures determined to be persistent and bioaccumulative. Each chemical substance or mixture placed on the priority list under section 6 would be evaluated for persistence and bioaccumulation, and chemical substances or mixtures so identified would be evaluated in accordance with the rule established pursuant to this section.

**Section 33. Expedited Action for Chemical Substances with Documented Risks.**

New section 33 would require expedited action under this title for listed chemical substances, on the grounds that the risk they pose to health and the environment has been well documented. Safety standard determinations for listed chemical substances and mixtures would be completed within one year after enactment, at which point the Administrator would take any required risk management actions to ensure that the listed chemical substances and mixtures meet the safety standard. Manufacturers and processors of listed chemical substances would not be required to submit a minimum data set under amended section 4(a), but would be required to submit the declaration required by section 8 within 6 months after enactment to inform the Administrator's determination. No new use of a listed chemical substance would be allowed, except for those specifically exempted.

**Section 34. Children's Environmental Health Program.**

New section 34 would establish a Children's Environmental Health Research Program to further the understanding of the vulnerability of children to chemical substances and mixtures. This section would establish an Interagency Science Advisory Board on Children's Health and Toxic Substances to provide independent advice, expert consultation, and peer review to the Administrator and Congress on issues relating to the implementation of this title with respect to protecting children's health. This section would direct the Administrator to coordinate with the Secretary of Health and Human Services to conduct biomonitoring studies and require disclosure of all known uses of chemical substances and mixtures found through such studies.

**Section 35. Reduction of Animal-Based Testing.**

New section 35 would require the Administrator to minimize the use of animals in testing of chemical

substances or mixtures by encouraging the use of existing data, grouping of chemical substances for testing, formation of industry consortia to reduce redundancy, use of existing methods that eliminate or reduce the use of animals, and the development and validation of emerging methods and models. The Administrator would be required to establish an Interagency Science Advisory Board on Alternative Testing Methods and develop a strategic plan to promote alternative methods. This section will also allow a manufacturer or processor to request adaptation or waiver of animal testing requirements.

### **Section 36. Safer Alternatives and Green Chemistry and Engineering.**

New section 36 would establish a program to create market incentives for the development of safer alternatives to existing chemical substances and mixtures that reduce or avoid the use or generation of hazardous substances. This program would require expedited review for new chemical substances or mixtures that manufacturers or processors claim are safer alternatives for existing chemical substances and mixtures used for the same purposes. The program would require the development of special designations, public awards, and rewards to recognize substances or products determined by the Administrator to be safer alternatives.

The section also requires establishment of a green chemistry research network, consisting of regional green chemistry and engineering centers, to support the development and adoption of safer alternatives to existing chemical substances and mixtures with an emphasis on those placed on the priority list.

### **Section 37. Cooperation with International Efforts.**

New section 37 requires the Administrator to cooperate in international efforts to develop a common electronic database or develop safer alternatives and establishes procedures to be implemented if or when the United States becomes a party to international agreements on the regulation of chemical substances and mixtures. This section would also require the phaseout of chemical substances and mixtures that are subject to mandatory bans under the Stockholm Convention and the LRTAP POPs Protocol.

### **Section 38. Data Quality.**

New section 38 would require the Administrator to establish and implement procedures to ensure data quality. The procedures would include inspection of commercial and private laboratories that develop data required under this Act, comprehensive data audits, and disclosure of funding sources.

### **Section 39. Hot Spots.**

New section 39 would require the Administrator to identify, assess, and develop action plans to address disproportionate exposures of residential populations in certain localities to toxic chemical substances and mixtures. The section would establish general definitions for disproportionate exposure and locality while requiring the Administrator to develop more specific criteria with public input and publish and update a list of affected localities. Within one year of publishing or updating the list, the Administrator would be required to develop and publish an action plan for each identified locality that includes the chemical substances and mixtures contributing to the disproportionate exposure.

The section would require an annual report to Congress on listing and action taken pursuant to these provisions.

### **Section 40. Application of this Act to Federal agencies.**

New section 40 would apply the requirements of the Toxic Substances Control Act to Federal agencies, departments, and instrumentalities that manufacture or produce chemical substances or mixtures.